

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL
INDUSTRY AVERAGE WHOLESALE
PRICE LITIGATION

MDL No. 1456

Civil Action: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO
01-CV-12257-PBS and 01-CV-339

Judge Patti B. Saris

**AMGEN INC.'S MOTION TO DISMISS PLAINTIFFS'
"CORRECTED AMENDED MASTER CONSOLIDATED
COMPLAINT" AND MEMORANDUM IN SUPPORT THEREOF**

Defendant, Amgen Inc. ("Amgen"), moves to dismiss plaintiffs' "Corrected Amended Master Consolidated Complaint" filed on July 16, 2004, because, despite being wordier, it still fails, like the three versions that preceded it, to allege specific facts to support the claim that Amgen was involved in the so-called "AWP scheme." ^{1/} Despite no fewer than four complaints filed over the course of more than two and one-half years – a period during which plaintiffs' investigators, experts and attorneys have had every opportunity to investigate their suspicions, interview physicians and industry insiders, and comb through the literally millions of pages of documents produced in this case by others, including Amgen's competitors – plaintiffs

^{1/} The July 16, 2004, Corrected AMCC is actually the *seventh* iteration of the complaint filed since this action began more than two years ago, and plaintiffs' *fourth* attempt to state a claim as to Amgen. The Court dismissed both the original Master Consolidated Complaint and plaintiffs' AMCC as to Amgen because of plaintiffs' failure to comply with Rule 9(b)'s specificity requirements. For ease of reference, Amgen will refer to the current operative pleading – the "Corrected Amended Master Consolidated Class Action Complaint Modified Per the Court's Instructions at the November 21, 2003 Hearing With Amgen Amendments" – as "the CAMCC."

remain unable to provide sufficiently detailed allegations of Amgen's supposed fraudulent manipulation of AWP and/or marketing of the so-called spread.

The CAMCC is significant not so much for what it says as for what it still fails to say. Plaintiffs still do not :

- point to any government investigation of Amgen,
- offer any example, let alone any practice, based on internal company documents or other materials, of Amgen's marketing of the so-called "spread,"
- identify a single misleading or fraudulent communication between Amgen and any of the compendia, or
- identify any unlawful inducement offered by Amgen to physicians, or point to any example of supposedly fraudulent pricing or other improper or allegedly unlawful conduct in connection with the marketing of its products.

Plaintiffs' have now clearly demonstrated their continuing inability to support their assertions by reference to particularized and adequately supported factual allegations, as required by Rule 9(b). In the absence of such allegations, Amgen should be dismissed from the CAMCC, and plaintiffs should not be given further leave to amend.

BACKGROUND AND THE CORRECTED AMCC

Amgen was one of only seven defendants dismissed by name from the Master Consolidated Complaint due to plaintiffs' failure to meet Rule 9(b)'s pleading requirements. *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 195 (D. Mass. 2003). And Amgen was one of only two defendants dismissed from the Amended Master Consolidated Complaint because of plaintiffs' continuing failure to comply with Rule 9(b). By Order entered on June 9, 2004, the Court again dismissed Amgen, giving plaintiffs 30 days to try again. On July 8, 2004, plaintiffs amended -- for the third time -- their allegations against

Amgen. (As noted, plaintiffs filed a “corrected” amended AMCC on July 16, correcting errors in the July 8 submission relating primarily to defendants other than Amgen.) Many of the additions in plaintiffs’ most recent amended pleading go to the completely unremarkable proposition Amgen operates in a competitive marketplace. *See* CAMCC ¶¶ 217-219. Like plaintiffs’ continued – if misplaced – reliance on a 1993 OIG Report (CAMCC ¶¶ 227B – 229) and Amgen’s supposed concealment of pricing information (CAMCC ¶¶ 229A – 230A), these allegations have been previously rejected by the Court as inadequate for purposes of Rule 9(b). What is left are plaintiffs’ “Specific Examples of AWP Abuse,” set out in paragraphs 222 through 227, which are neither “specific” nor examples of improper or fraudulent conduct.

ARGUMENT

The CAMCC adds nothing in the way of additional detail regarding Amgen’s supposed involvement in the so-called AWP scheme. And, what little it does add involves at most allegations of misconduct by others or pertains largely to alleged conduct that occurred *after* the filing of the complaint in this matter, and thus can hardly serve as a basis for inferring fraud. In either case, the CAMCC does not remedy the deficiencies of plaintiffs’ prior complaints..

I. Plaintiffs’ Allegations Regarding the Marketing of Aranesp® Do Not Provide New Details of Amgen’s Supposed Fraud.

A. Aranesp® was not even introduced until after this action was filed.

Preliminarily, plaintiffs’ assertions regarding Aranesp® pricing make clear that the alleged conduct did not occur until 2002 – *after* this case was filed. *See* CAMCC ¶ 224B. Plaintiffs, therefore, were aware of the alleged fraudulent scheme as a matter of law. Because fraud requires that plaintiffs must have been misled by, or justifiably relied upon, defendants’

representations, *see, e.g., Sands v. Ridefilm Corp.*, 212 F.3d 657, 663 (1st Cir. 2000), alleged acts that took place after plaintiffs' obvious discovery of the supposed scheme are neither actionable nor relevant, and need not even be considered by the Court. *See also U.S. ex rel. Durholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999) (in False Claims Act context, government knowledge precludes a claim of fraud); *U.S. ex rel. Grynberg v. Praxair, Inc.*, 207 F.Supp.2d 1163, 1178 (D. Colo. 2001) (same).

B. Discounts are not unlawful.

Plaintiffs devote nearly two pages of the CAMCC to advertised contract discounts and rebates available to hospital customers for Aranesp®. There is, however, nothing inappropriate or unlawful about the offering or provision of discounted prices, so long as they are properly accounted for. In fact, the discount safe harbor to the federal anti-kickback statute is specifically intended to preserve and protect precisely this kind of negotiated savings, the government no doubt recognizing that discounts generally lower prices and are in the public interest. 42 U.S.C. § 1320a-7(b)(3)(A); 42 CFR 1001.952(h). Significantly, plaintiffs do not specifically tie these discounts to an inflated AWP, or to an unlawful marketing of the so-called spread. While the Court has not required plaintiffs to allege a specific spread in every instance, in the absence of other allegations upon which fraud properly can be inferred, specific allegations of how a reported AWP was unlawfully inflated, or of how Amgen engaged in the unlawful marketing of the spread between AWP and actual sales price is required. ^{2/} In the

^{2/} Plaintiffs' efforts to elevate general information regarding reimbursement to the level of promoting AWP and the "spread" is unavailing. Plaintiffs allege, for example, that Amgen provides information on its website regarding Medicare reimbursement based upon AWP. CAMCC ¶ 222. Plaintiffs' efforts to read something sinister into this practice is baseless. The website does nothing to endorse the use of AWP in connection with reimbursement, does not identify any spread, market the spread, or make any suggestion regarding profit or so-called "return to practice" – as plaintiffs have alleged as to other companies. Instead, the website

absence of such specifics, an allegation that a company merely offered volume discounts to customers hardly supports an inference of fraud and certainly does not comply with Rule 9(b).

II. **Alleged Conduct of Other Defendants Cannot be Attributed to Amgen.**

In dismissing Hoffman LaRoche – and implicitly in dismissing Amgen -- the Court rejected the notion of “guilt by association,” recognizing that Rule 9(b) requires particularized factual allegations as to *each* defendant. *See, e.g., Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 877-78 (1st Cir. 1991). No doubt in response, plaintiffs have eliminated allegations found in the AMCC that had expressly asked the Court to draw the “logical inference” that because Amgen operates in a competitive industry, and because other companies were allegedly marketing the spread or manipulating the AWP for the various of their products, then Amgen must also have been engaged in such conduct. *See* AMCC ¶ 221. Nevertheless, that is precisely the inference on which the CAMCC continues to rely.

This is nowhere more apparent than in connection with plaintiffs’ allegations regarding the supposed marketing of the spread in connection with Aranesp®. Unable to point to even a single example of such conduct by an Amgen representative, plaintiffs contend that

Ortho was heavily engaged in its own conduct directed at marketing the spread and Amgen needed to respond in kind.... *Ortho*, at national sales meetings, authorized its sales and marketing representatives to provide free samples as a means of lowering acquisition costs to providers. *Ortho* also used inducements such as educational and promotional grants to win over clinics and other providers and as credit memos which were inducements for a clinic or provider to use Procrit[®] exclusively.

CAMCC ¶ 224B (emphasis added). Then, without benefit of any reference to source, timeframe, individuals involved, or specific example, plaintiffs baldly assert: “Amgen sales representatives

merely provides information to customers regarding reimbursement. Given that numerous drugs are reimbursed in the Medicare Part B context and perhaps in the private setting based on AWP, it is foolhardy to assert that Amgen or any other manufacturer engaged in fraud merely by making AWP’s available to third parties on the company’s website. .

learned of these efforts and reacted to them by offering inducements of their own. These inducements included rebates based upon volume used by the practitioner.” ^{3/} Pleading such important facts in such an offhand and conclusory manner, particularly at this late date, flies in the face of one of Rule 9(b)’s primary purposes – to “give notice to defendants of the plaintiffs’ claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage ‘strike suits,’ and to prevent the filing of suits that simply hope to uncover relevant information during discovery.” *See Karvelas v. Mesrose-Wakefield Hosp.*, 360 F.3d 220, 222 (1st Cir. 2004), citing *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir.1996).

By the same token, plaintiffs’ two references to documents allegedly created and/or produced by Immunex and Centocor do nothing to support plaintiffs’ claims against Amgen. *See* CAMCC ¶¶225A, 225B. With regard to Immunex, the internal memorandum referred to in paragraph 225A of the CAMCC does nothing more than compare available discounts for Immunex’s product, Leukine®, and Amgen’s Neupogen®. The allegation, however, is silent as to how the referenced discount price(s) compared to AWP, how Amgen calculated its AWP, or whether Amgen was in any way engaged in the marketing of the spread. Similarly, the Centocor memorandum referred to in paragraph 225B was plainly not prepared by Amgen and, at best, is mere speculation by a third party regarding Amgen sales practices. Whatever such memoranda may reveal about practices at the company responsible for authoring them, they fail to support the allegation that *Amgen* was involved in the same conduct. In much the same manner as the Court rejected plaintiffs’ efforts to attribute to Hoffman-LaRoche

^{3/} The CAMCC contains a number of similar and wholly conclusory allegations. For example, and again without reference to any *facts* (the “who, what, when, where, and how of any alleged scheme), plaintiffs assert in self-serving fashion that “Amgen sales representatives either handed out calculations show the spread off AWP, ... or orally reviewed such profits with physicians. CAMCC ¶ 221A. *See also* CAMCC ¶ 223A (“It was intended by Amgen’s top sales executives that its sale force would use this “profit” as a basis for marketing Aranesp.”).

allegations against another co-defendant, the Court should reject plaintiffs' invitation to attribute to Amgen an outside third party's surmise about what Amgen may or may not have been doing in connection with the marketing of its products. Centocor's or any other company's internal speculation is hardly the sort of "internal company document" that this Court had in mind in setting the bar that plaintiffs must clear in order to link a company to an alleged multi-billion dollar scheme to defraud.

III. Plaintiffs' Undefined "Real AWP" Adds Nothing to the Mix.

This Court has held since the outset that plaintiffs must, among other things, "clearly and concisely allege with respect to each defendant" the "allegedly fraudulent AWP for each drug." *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d at 194. Implicit in this requirement is that plaintiffs must spell out precisely why they contend a reported AWP was fraudulent, anchoring it to a specific factual allegation consistent with the requirements of Rule 9(b). In many cases involving allegations against other defendants, plaintiffs have sought to comply with the Court's directive by relying on government audits or investigations, which at least arguably determined a "true" average price, and measured that figure against the reported AWP to determine a "spread." In allegations against still other defendants, plaintiffs rely on internal company documents, or documents disseminated by defendants and left with physicians in connection with marketing efforts. In Amgen's case, however, plaintiffs simply make up an undefined "Real AWP" against which they have come up with their own self-serving assessment of the so-called "spread." *See* CAMCC ¶ 226A. Merely taking the published AWP for a particular Amgen product and comparing that to a figure that is not defined, explained or tethered to a concrete figure, is plainly inadequate and provides

absolutely no insight as to the factual basis for believing that Amgen engaged in unlawful AWP manipulation.

But even taking these numbers at face value, they fail to demonstrate a reasonably sufficient basis for inferring fraud. Based upon the figures provided, the so-called spread fluctuates indiscriminately from year to year, from 27% one year, to 34% the next year and back again. *Id.* This is hardly the stuff of a well-orchestrated and consciously implemented fraudulent scheme that, according to plaintiffs, is evidenced by ever-increasing AWP's and ever-increasing spreads corruptly intended to drive market share. If plaintiffs' theory were correct, and the reported AWP was consistently increased even as actual prices fell, the spread similarly would have increased consistently over time. ^{4/}

At the end of the day, plaintiffs' amendments simply increase the length, but not the substance, of their allegations against Amgen. All that the plaintiffs are able to muster are a handful of allegations regarding periodic price increases (which Amgen is entirely within its rights to make) and the offering of discounts to customers (which for the most part pertain to pricing decisions made *after* the filing of this action, and which are, in any event, entirely lawful), buttressed by the simple fact that Amgen operates in a competitive industry. ^{5/} Even after

^{4/} Plaintiffs' allegations are non-sensical in other respects as well. The notion that Amgen "inflated" spreads for Epogen® in order to increase market share, *see* CAMCC ¶¶ 226B-227, makes little sense given that Epogen® is marketed by Amgen only for use in connection with ESRD – a market in which it effectively has no competitor. Similarly, increasing the spread for Enbrel® would do little to increase Amgen's market share for that product given both its and Immunex's historical inability to produce adequate supplies of the product to meet demand.

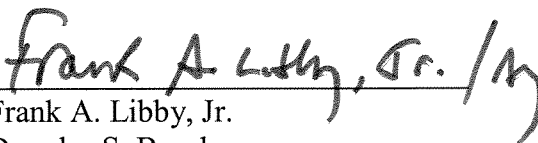
^{5/} In its apparent zeal to demonstrate such competition, and perhaps indicative of the care that has gone into the crafting of many of its factual allegations, even at this late date, plaintiffs' amendments erroneously include the contention that "[c]ompetition also existed between Amgen's Remicade and Immunex's Embrel" [sic; the product name is Enbrel®]. CAMCC ¶ 219A. Remicade is, of course, manufactured and distributed by Centocor, Inc., an operating division of Johnson & Johnson.

multiple tries, plaintiffs are still unable to plead, with particularity, how the AWP's for Amgen products reported by the Compendia are supposedly fraudulent. In the absence of such specifics, no adequate basis exists for keeping Amgen in this case.

CONCLUSION

For the reasons set forth herein, Amgen respectfully submits that the allegations set forth in the CAMCC against Amgen should be dismissed with prejudice and without further leave to amend.

Respectfully submitted,



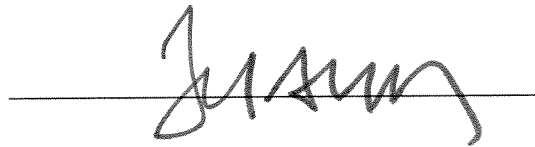
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Dated: July 26, 2004

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Amgen Inc.'s Motion to Dismiss Plaintiffs' "Corrected Amended Master Consolidated Complaint" and Memorandum in Support Thereof was, this 26 day of July, 2004, served electronically via Verilaw on all counsel of record in this matter.

A handwritten signature in black ink, appearing to read "J. A. Smith", is written over a horizontal line.